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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,190	02/28/2002	Pia M. Challita-Eid	511582003420	7796

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EXAMINER

BLANCHARD, DAVID J

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,190

Applicant(s)

CHALLITA-EID ET AL.

Examiner

David J. Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-7, 9, 10, 12, 13, 15, 48, 49, 54 and 78-82 is/are pending in the application.
- 4a) Of the above claim(s) 15, 48, 49 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-7, 9, 10, 12, 13 and 78-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 4-7, 9-10, 12-13, 15, 48-49, 54 and 78-82 are pending.

Claims 1-3, 8, 11, 14, 16-47, 50-53 and 55-77 have been cancelled.

Claim 12 has been amended.

Claims 15, 48-49 and 54 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 4-7, 9-10, 12-13 and 78-82 are under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

4. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claim.

Response to Arguments

5. The objection to the disclosure for containing embedded hyperlinks and/or other form of browser-executable code is maintained.

The response filed 2/22/2005 has been carefully considered, but is deemed not to be persuasive. The response submitted an amendment to remove the browser-executable code and requested the objection be withdrawn. In response to applicant's

amendment, the hyperlinks beginning with "www" remain active hyperlinks and the objection is maintained. Applicant may overcome this objection by spelling out the acronym "www" as "world wide web" or by any other means, which inactivates the hyperlinks.

6. The rejection of claims 4-7, 9-10, 12-13 and 78-82 under 35 U.S.C. 102(e) as being anticipated by Tang et al is maintained.

The response filed 2/22/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that Tang discloses thousands of sequences and Tang does not provide any specific teachings with respect to SEQ ID NO:3188, which is identical to residues 16-205 of SEQ ID NO:3 of the present claims and applicant references Example 4 at pages 98-99 of Tang as not disclosing the specific nucleic acid encoding SEQ ID NO:3188. Applicant also argues that Tang describes methods of making antibodies, with apparently no description whatsoever of what those antibodies should be raised against. In response to the arguments, applicant is reminded that references are part of the literature of the art, relevant for all they contain including nonpreferred embodiments (MPEP 2123). As set forth in the previous Office Action Tang teaches the protein of SEQ ID NO:3188 that is identical to amino acid residues 16-205 of SEQ ID NO:3 of the present claims and Tang teaches antibodies (i.e., monoclonal, polyclonal, human, humanized, single-chain antibodies and antibody fragments; pages 76 and 78-80) and immunoconjugates (pages 83-84) that bind the proteins of the invention (i.e., SEQ ID NO:3188) (page 74) hence, Tang anticipates the claimed invention.

Applicant appears to suggest that the hybridoma and antibodies of Tang are not identical to the instantly claimed hybridoma and antibodies because the protein of SEQ ID NO:3188 taught by Tang is only 190 amino acid residues and does not teach the N-terminal 15 amino acid residues of SEQ ID NO:3 instantly claimed. Consistent with the examiner's position in the previous Office Action and in response to the above argument by applicant, the Patent and Trademark Office does not have the facilities for examining and comparing the claimed hybridoma and antibody with the hybridoma and antibodies of Tang et al, thus, the burden of proof is upon Applicant to show a distinction between the structural and functional characteristics of the claimed hybridoma and antibody and the hybridoma and antibodies of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response also argues that Tang does not discuss any utility for the protein of SEQ ID NO:3188. In response to this argument, applicant is reminded that utility is not required for anticipation (MPEP 2122).

Therefore, the rejection of claims 4-7, 9-10, 12-13 and 78-82 under 35 U.S.C. 102(e) as being anticipated by Tang et al is maintained.

7. The rejection of claims 4-7, 9-10, 12-13 and 78-79 under 35 U.S.C. 102(e) as being anticipated by Edwards et al is maintained.

The response filed 2/22/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that Edwards et al discloses 19,335 sequences

and the cited sequence of SEQ ID NO:4959, which shares sequence identity with SEQ ID NO:3 of the instant claims is not specifically mentioned in the specification of Edwards, except in the sequence listing. In response to this argument, applicant is reminded that the use of patents as references is not limited to what patentees describe as their own inventions or to problems with which they bare concerned. They are part of the literature of the art, relevant for all they contain (MPEP 2123). Applicant also argues that SEQ ID NO:4959 of Edwards only shares 57.1% amino acid identity (i.e., 117 amino acid residues out of 205) with the instantly claimed protein of SEQ ID NO:3. Although not explicitly stated, this argument appears to suggest that applicant's position is that the antibodies of Edwards would not bind the presently claimed protein of SEQ ID NO:3. As set forth in the previous Office Action Edwards teaches the protein of SEQ ID NO:4959 that is identical to amino acid residues 1-117 of SEQ ID NO:3 of the present claims and Edwards teaches antibodies that specifically bind to the protein of SEQ ID NO:4959 or epitope-containing fragments thereof (column 20, lines 30-47) and Edwards teaches that the antibodies may be monoclonal, human, humanized, single-chain antibodies, antibody fragments as well as immunoconjugates (columns 72-75). As stated in the previous Office Action, it is the examiner's position that the antibodies of Edwards that bind to the protein of SEQ ID NO:4959 would necessarily bind residues 1-117 of SEQ ID NO:3 because the sequences are identical. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed hybridoma and antibody with the hybridoma and antibodies of Edwards et al, the burden of proof is upon Applicant to show a distinction between the structural and functional

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characteristics of the claimed hybridoma and antibody and the hybridoma and antibodies of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Therefore, the rejection of claims 4-7, 9-10, 12-13 and 78-79 under 35 U.S.C. 102(e) as being anticipated by Edwards et al is maintained.

8. The rejection of claims 4-7, 9-10, 12-13 and 78-82 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al in view of Thorpe et al is maintained.

The response filed 2/22/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that Edwards fails to disclose antibodies to the specific protein of the instant claims and there is no motivation alone to make antibodies to each of the thousands of sequences described and the addition of Thorpe does not supply any guidance to select one specific sequence out of the myriad of sequences of Edwards. In response to this argument and as discussed above, Edwards teaches an antibodies that specifically bind to the protein of SEQ ID NO:4959 or epitope-containing fragments thereof (column 20, lines 30-47) and Edwards teaches that the antibodies may be monoclonal, human, humanized, single-chain antibodies, antibody fragments as well as immunoconjugates (columns 72-75). Again, it is the examiner's position that the antibodies of Edwards that bind to the protein of SEQ ID NO:4959 would necessarily bind residues 1-117 of SEQ ID NO:3 because the sequences are identical. Thorpe was cited for teaching that conjugating antibodies with radioactive isotopes, chemotherapeutic agents and toxins is known and routine to one of ordinary skill in the

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art at the time the invention was made and it would have been obvious to conjugate these agent to the antibody of Edwards et al for diagnostic and therapeutic methods.

Therefore, the rejection of claims 4-7, 9-10, 12-13 and 78-82 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al in view of Thorpe et al is maintained.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at


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(571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D
PRIMARY EXAMINER